BJCP British Journal of Clinical Pharmacology

DOI:10.1111/j.1365-2125.2012.04413.x

Balanced prescribing – principles and challenges

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Keywords
adverse drug reactions, benefit to harm balance, medication errors, prescribing

Received
9 November 2011

Accepted
4 May 2012

Balanced prescribing is a process that recommends a medicine appropriate to the patient's condition and, within the limits created by the uncertainty that attends therapeutic decisions, a dosage regimen that optimizes the balance of benefit to harm. The essential steps in achieving this are (a) careful attention to the history, examination, and investigation of the patient's condition and drug therapy, (b) accurate diagnosis, (c) detailed attention to prescribing the dosage regimen in the light of the therapeutic goal, (d) careful writing of the prescription and (e) regular monitoring of therapy, including attention to beneficial outcomes, adverse reactions, and patient adherence. The two major requirements in determining the dosage regimen are (1) understanding the pathophysiology of a health problem and matching it to the mechanisms of action of the relevant medicines and (2) assessing the benefit to harm balance of the therapy, although the difficulties in doing this in the individual are great. Major challenges in prescribing include provision of adequate education for all prescribers early in their undergraduate training and maintaining their expertise after graduation, obtaining evidence to inform appropriate monitoring of therapy, reducing the incidence of medication errors, and providing high quality information that will at the same time guide prescribing decisions and be sufficiently flexible to allow prescribers to tailor therapy to the needs of the individual patient. Careful attention to all facets of prescribing can improve the chances of benefit, reduce the risks of adverse reactions and interactions, and enhance adherence to therapy.

Introduction – balanced prescribing

Balanced prescribing is a process that recommends a medicine appropriate to the patient's condition and, within the limits created by the uncertainty that attends therapeutic decisions, a dosage regimen that optimizes the balance of benefit to harm [1]. The British Pharmacological Society's 'Ten principles of good prescribing' [2], are shown in Table 1.

The steps that are necessary to achieve these principles are outlined in Table 2.

In addition to the skills required to reach a diagnosis through the history, examination, and investigations (steps 1 and 2), the prescriber needs to know where to seek evidence regarding the appropriateness, effectiveness, and interactions of medications, in order to be able to devise a suitable dosage regimen (step 3), to write a clear and accurate prescription (step 4), to monitor the outcomes, both beneficial and harmful, in order to make appropriate adjustments to the regimen (step 5), and to be able to discuss the diagnosis and treatments, including adverse reactions and interactions, with patients and carers (at all steps), encouraging understanding and adherence when possible [3]. At all stages in this process two over-riding principles apply when selecting a specific medication in an appropriate dosage regimen:

Principle 1

Understanding the pathophysiology of a health problem and matching it to the mechanisms of action of the relevant medicines is key to appropriate prescribing.

Principle 2

The benefit to harm balance of the therapy should ideally be favourable, although the difficulties in assessing this in the individual are great.

Steps 1 and 2 (Table 2) have been discussed in detail elsewhere [4–6]. For more details about the points dealt with here see [7].

Table 1
Ten principles of good prescribing

1. Be clear about the reasons for prescribing
• Establish an accurate diagnosis whenever possible (although this may often be difficult)
• Be clear in what way the patient is likely to gain from the prescribed medicines
2. Take into account the patient's medication history before prescribing
• Obtain from the patient, their carers, or colleagues an accurate list of current and recent medications (including over the counter and alternative medicines), prior adverse drug reactions, and drug allergies
3. Take into account other factors that might alter the benefits and harms of treatment
• Consider other individual factors that might influence the prescription (e.g. physiological changes with age and pregnancy; impaired kidney, liver, or heart function)
4. Take into account the patient's ideas, concerns, and expectations
• Seek to form a partnership with the patient when selecting treatments, making sure that they understand and agree with the reasons for taking the medicine
5. Select effective, safe, and cost-effective medicines individualized for the patient
• The likely beneficial effect of the medicine should outweigh the extent of any potential harms, and whenever possible this judgement should be based on published evidence
• Do not prescribe medicines that are unlicensed, 'off-label', or outside standard practice unless satisfied that an alternative medicine would not meet the patient's needs (this decision will be based on evidence and/or experience of their safety and efficacy)
• Choose the best formulation, dose, frequency, route of administration, and duration of treatment
6. Adhere to national guidelines and local formularies when appropriate
• Be aware of guidance produced by respected bodies (increasingly available via decision support systems), but always consider the individual needs of the patient
• Select medicines with regard to costs and needs of other patients (health care resources are finite)
• Be able to identify, access, and use reliable and validated sources of information (e.g. the British National Formulary), and evaluate potentially less reliable information critically
7. Write unambiguous legal prescriptions using the correct documentation
• Be aware of common factors that cause medication errors and know how to avoid them
8. Monitor the beneficial and adverse effects of medicines
• Identify how the beneficial and adverse effects of treatment can be assessed
• Understand how to alter the prescription as a result of this information
• Know how to report adverse drug reactions (in the UK via the Yellow Card scheme)
9. Communicate and document prescribing decisions and the reasons for them
• Communicate clearly with patients, their carers, and colleagues
• Give patients important information about how to take the medicine, what benefits might arise, adverse reactions (especially those that will require urgent review), and any monitoring that is required
• Use the health record and other means to document prescribing decisions accurately
10. Prescribe within the limitations of your knowledge, skills, and experience
• Always seek to keep the knowledge and skills that are relevant to your practice up to date
• Be prepared to seek the advice and support of suitably qualified professional colleagues
• Make sure that, where appropriate, prescriptions are checked (e.g. calculations of intravenous doses)

A note on nomenclature

The English word 'prescription' is ambiguous: it can mean both (a) the act of prescribing (which includes the decision-making process that underlies it) and (b) the written form that contains the prescribing instructions. Here I shall use the word only in its latter meaning and use 'prescribing' for the former.

Matching the pathophysiology of the problem to the mechanism of action of the therapy

Some examples illustrate this principle.

In managing infections, one's prescription depends on the pathology, i.e. the infecting organism. If the organism is not known, one takes an educated guess based on the likely organism. For example, one might prescribe ampicillin plus erythromycin for a patient with pneumonia, since the most likely infecting organisms are *Streptococcus pneumoniae* and *Legionella pneumophila*. This strategy will fail in the rarer cases when other organisms are responsible (e.g. *Klebsiella pneumoniae* or meticillin-resistant *Staphylococcus aureus*), although in those cases one's suspicion may be aroused by unusual features of the case (e.g. the colour of the sputum or evidence of abscesses on a chest radiograph).

A fast ventricular rate in atrial fibrillation that is due to ischaemic heart disease will respond to digoxin but if it is due to hyperthyroidism it will not.

Hypokalaemia due to diuretics can be avoided by using spironolactone. However, hypokalaemia in Liddle's syndrome, which is due to a channelopathy, will not respond and amiloride is needed instead.

This principle, illustrated by these examples, applies to the mechanisms of both benefits and harms (adverse reaction or interactions). For example, although the exact mechanism whereby abacavir causes allergic rashes is not known, it is partly understood, in that it is most likely to

Table 2
Five steps to balanced prescribing

Step	Comment
1. History, examination, and investigations	Involving not only the condition to be treated, but also medications that the patient is taking or has taken
2. Diagnosis	Important for choosing therapy that is appropriate to the patient's condition, including susceptibility factors that alter benefits and harms
3. Prescribing the dosage regimen	Should be tailored to the condition to be treated, the patient's individual characteristics (e.g. susceptibilities to adverse drug reactions and interactions), and, if possible, the patient's preferences
4. Writing the prescription	The practical matters related to giving instructions about the dosage regimen clearly and unambiguously, avoiding medication errors
5. Monitoring	Both short term, in order to determine if there is a favourable response, and long term, in order to modify treatment when necessary as time progresses, keeping the therapeutic goal in mind; this includes encouraging adherence

occur in those who carry the HLA B*5701 polymorphism and can be avoided by choosing another antiretroviral drug in such individuals [8].

The benefit to harm balance in general and in particular

There are two aspects to the benefit to harm balance of an intervention, general and particular. The general approach to the analysis is illustrated in Table 3. If a medication is highly efficacious in a life-threatening condition, if adverse reactions are rare and trivial, and if no other interventions are possible, the benefit to harm balance is highly favourable. For example, N-acetylcysteine is highly effective for preventing liver damage after a paracetamol overdose, adverse reactions are uncommon and usually mild, and there are no other agents that are as effective.

At the opposite extreme, the benefit to harm balance is highly unfavourable if a medication is poorly efficacious in a trivial condition, if adverse reactions are frequent and serious, and if there are other better and safer interventions. For example, amidopyrine, used in some countries to treat headache, can cause severe bone marrow depression, and there are much safer and equally effective alternatives.

In practice, most cases lie between these two extremes. Some can be easily assessed, others not. However, such decisions can be made on the basis of evidence from high quality randomized controlled trials or observational studies [9], in which data on efficacy and harms are collected. The benefit to harm balance, rather than benefits alone, is the basis on which medications should be approved for clinical use by regulatory agencies, and this is increasingly coming to be the case [10].

However, assessing the benefit to harm balance in the individual case is much more difficult, for several reasons.

Although it is generally assumed that the results of a trial apply to those who took part, or to those like them (internal validity), the result merely gives an average expectation of the outcome. Even someone who was part of the original group studied may be at one extreme of the distribution and may not respond in the same way as the average participant.

The appropriateness of extrapolating the average result to those who are not representative of those originally studied (i.e. adaptability of the results or external validity) is obviously even more uncertain. In addition, different patients may have different preferences, which should be taken into account.

There is currently no good way of making the decision about the likely benefit to harm balance in an individual before embarking on therapy. However, features of the patient, such as genetics, age, sex, physiology (e.g. obesity, pregnancy), co-morbidities (e.g. renal or hepatic impairment), and other medications (in interactions), all of which confer different susceptibilities to both benefits and harms, can be used to make preliminary predictions.

Knowledge of the numbers needed to treat to produce benefit (NNT_B) or harm (NNT_H) can also help in assessing the benefit to harm balance [11]. Some medicines are more likely to cause adverse reactions when given in dosages that are within or only a little above the usual therapeutic range. These medicines have a low therapeutic index. They include aminoglycosides, anticoagulants, anticonvulsants, antihypertensive drugs, cardiac glycosides, cytotoxic and immunosuppressant drugs, oral contraceptives, and drugs that act on the central nervous system. Take special care when prescribing such medications.

Formulating the dosage regimen

The problem of adaptability of trial results to individuals implies that every act of prescribing is an experiment. With a few exceptions (such as glucocorticoids and carbimazole), it is usual to start with a low dose and increase gradually, monitoring for outcomes, both beneficial and harmful, to guide changes in dose. The initial prescribing decision is not the end of therapy. It should be repeatedly scrutinized.

Nine questions guide balanced prescribing. They deal with **I**ndication, **E**fficacy, **D**osage, **O**verlapping medications, **I**nteractions, **D**iseases, **O**rders, **P**eriod (duration) of treatment and **E**xpense (mnemonic I.E. DO I DOPE?). They are listed in Table 4.

Here are some notes on the dosage regimen:

- Generally, start with a dosage at the lower end of the recommended range. Exceptions to this rule include

Table 3

Assessing the benefit to harm balance – the two extreme cases

		Harms		Other drugs		
Seriousness of the condition	Drug efficacy	Seriousness	Risk	Efficacy	Safety	Benefit to harm balance
Life-threatening	High	Trivial	Low	Poor	Poor	Favourable
Trivial	Poor	Serious	High	Good	Good	Unfavourable

Table 4

Nine guidelines for prescribing and their related questions

Guideline	Related question
Indication	Is the medication indicated for the problem? If so, is it needed in this case?
Efficacy/ Effectiveness	Is it efficacious (and likely to be effective) in the condition? This will depend initially on reported efficacy from trials; later it may be possible to judge effectiveness in the individual during monitoring.
Dosage	What is the correct dosage regimen?
Overlapping medications	Is there unnecessary duplication with other effective medicines?
Interactions	Are there clinically important drug–drug, drug–food, or drug–device interactions?
Diseases	Are there clinically significant drug–disease interactions?
Orders	What are the correct and practical orders for administration of the medicine?
Period of administration	What is the proper duration of therapy?
Expense	Is the medicine the least expensive alternative (i.e. is it cost-effective)?

glucocorticoids and carbimazole, which are begun in high dosages and then reduced to maintenance dosages. Some drugs (for example, digoxin, warfarin and amiodarone) are given in a loading dose followed by a maintenance dose.

- Increase the dosage slowly, monitoring the therapeutic effect at regular intervals and looking for adverse effects and reactions.
- If adverse effects or reactions occur, reduce the dosage or try another formulation or another medicine. Sometimes adverse reactions can be avoided by combining medicines (for example, azathioprine reduces glucocorticoid dosage requirements in immunosuppression).
- Think of drug interactions and avoid potentially dangerous combinations.
- Remember that elderly people are more susceptible to adverse drug reactions and are likely to be taking more medicines than younger patients, increasing the risk of interactions.
- Remember that diseases can alter dosage requirements.
- Take particular care with medicines that have a low therapeutic index, which means that a small change in dosage can have a large effect.
- Special problems include renal or hepatic impairment, breast feeding, and pregnancy.
- Prescribing for children poses special problems. Indications are often not licensed in children, even though they may be licensed in adults. Other features for which a medicine may not be licensed in children include the dose and route of administration. The use of the medicine for such indications or in ways that are not specified is termed 'off-label'.

Polypharmacy (which is usually defined as prescribing four or more medications for a patient) is often regarded as poor prescribing, but it is only so if it is inappropriate. Polypharmacy is appropriate, for example, in the treatment of tuberculosis and diabetes mellitus, and in the prevention of cardiovascular disease. If each medication that a patient takes has been prescribed appropriately (which includes absence of interactions between them), polypharmacy should not be a problem. However, the more medicines a patient takes the more difficult it is for them to adhere to therapy.

Writing the prescription

A prescription should be precise, accurate, clear, and readable. It should be sufficient for a nurse to administer a medicine accurately in hospital, or for a pharmacist to provide a patient with both the correct medicine and the instructions on how to take it. There are four common types of prescription:

- Prescriptions in general practice
- Hospital prescriptions for inpatients
- Hospital prescriptions for an external pharmacy
- Private prescriptions.

Here is the information that must be given on a prescription:

- Date
- Identification of the patient
- Name of the medication
- Formulation
- Dose

- Frequency of administration
- Route and method of administration
- Amount to be supplied
- Instructions for labelling
- Prescriber's signature.

Guidance on writing a prescription is to be found in standard texts, including, in the UK, the British National Formulary (BNF). Here are some notes:

- The patient should be clearly identified. In hospital give the surname, one forename and other initials, and the hospital case number. If there are two patients of the same name in the ward, say so. On prescriptions for pharmacies outside hospital give the name, one forename and other initials, and the address. For children younger than 12 years and adults older than 60 years, give the age (in years and months if younger than 5 years).
- Prescriptions should ideally be typewritten; if this is not possible, write carefully and clearly. The name of the medication should not be abbreviated and should be written in upper case letters. It is usually recommended that the international non-proprietary name should be used, but modified-release formulations of some drugs need to be prescribed by brand name, because different formulations have different effects. These include lithium, theophylline, nifedipine, and diltiazem.
- The formulation should be clearly specified, for example tablets or oral suspension.
- The dose should be clearly specified; decimal points should be avoided if possible; grams (g), milligrams (mg) and millilitres (ml or ml) can be abbreviated, but micrograms and nanograms should always be written in full. For some drugs a maximum dose should be specified (for example colchicine in gout)
- The route of administration should be clearly specified, unless it is obvious (for example 'beclometasone inhaler, two puffs bd'). The method of giving a medicine intravenously should be specified (for example, as a single undiluted bolus injection, as an infusion in a small volume of saline over a few minutes, or in a larger volume over a longer period of time, giving the precise rate of flow if necessary).
- The dosage interval should be clearly specified. Prescriptions for medicines that are given as required should have exact instructions about maximum frequency, for example 'paracetamol tablets, two as required, not more often than four-hourly.'

Monitoring and adjusting therapy

Detailed consideration of the principles of monitoring therapy is beyond the scope of this article. Here are some notes [12].

Monitoring may relate to therapeutic benefit or to adverse effects or reactions. Methods include symptoms, frequency of use, biomarkers of therapeutic or adverse outcomes (such as INR for warfarin, peak expiratory flow rate in asthma, and electrolytes for diuretics), and numbers of emergency visits or hospital admissions. The frequency of monitoring depends on the test and can be triggered by risk indicators. If problems are detected by monitoring, education, aids to adherence (for example, drug packaging aids), aids to drug delivery (for example, spacer devices), changes in medication (for example, dosage or timing), or environmental changes may be needed.

Having decided that treatment needs to be monitored and having selected the appropriate test, a therapeutic target should be set, for example the target blood pressure in hypertension or blood glucose concentration in diabetes. The patient should be informed about the intended outcome of therapy and the importance of trying to achieve the target and warned about possible common or serious adverse reactions, particularly those that they can detect for themselves (for example, a sore throat as a marker of neutropenia). At follow-up assess the success of the intervention in relation to the target and adverse effects or reactions. Set a new target if necessary and repeat the process.

Discussing treatment with patients and carers

Always try to discuss the treatment with the patient or carers, or both, in simple terms, emphasizing the need for treatment. Stress the importance of adhering to therapy, which can be improved by careful explanation of its importance and by prescribing medicines that can be taken only once or twice a day.

Sometimes specific pieces of information are necessary. Examples include instructions on how to use an inhaler or eye drops or information on when to expect benefit (which may be delayed), on timing of administration, unwanted reactions or interactions, or methods of self-monitoring.

Challenges

The principles of balanced prescribing enunciated above pose several challenges.

Education

The provision of teaching in clinical pharmacology and therapeutics is an important part of encouraging balanced prescribing. This applies not only to medical students and doctors, but also to other prescribers, who nowadays, at least in the UK, include pharmacists and nurses. Since an understanding of the pathophysiology of disease and

diagnostic methods is important, these matters should form a part of the education of those groups. Prescribers who are not clinically qualified should be encouraged to liaise with clinicians whenever necessary. This is part of the principle (Table 1) that one should not prescribe outside the limitations of one's knowledge, skills, and experience. Teaching should include instruction on how to read primary literature and guidelines critically.

Several studies have shown that newly qualified doctors in the UK are poorly prepared to be prescribers [13–16]. In the hope of repairing this deficiency, the Deans of UK Medical Schools have agreed that prescribing abilities should be assessed in the final year of undergraduate training [17]. In conjunction with this, an e-learning program has been developed by the British Pharmacological Society and is to be made available free to all medical students in the UK [18].

Revalidation of qualified prescribers should include assessment of their prescribing abilities and a set of safety indicators to facilitate this in general practice has been developed [19].

Information

Clear unambiguous information is an important prerequisite to support balanced prescribing. In the UK this is provided by publications such the BNF and the BNF for Children, which are produced with the UK primarily in mind, but also with an eye to international use [20].

Guidelines produced by learned societies and national bodies can be useful in directing clinical practice in individual cases. However, there are times when guidelines do not apply and prescribers need to be alert to the needs of the individual patient. For their part, those who produce guidelines need to be aware of this and to tailor their guidelines to allow flexibility. Local medicines and therapeutics committees should have the power to dictate local policy in the light of national guidelines [21].

Monitoring

Unless drug therapy is carefully monitored during long term treatment, appropriate changes to dosage regimens may not be made and adverse reactions or reduced efficacy can result. However, there is a dearth of satisfactory information on how the long-term effects, beneficial and harmful, of most medications should be monitored and what actions should be taken as a result [22, 23].

Medication errors

Medication errors are a continuing source of adverse drug reactions and are difficult to eradicate. For example, in one UK study of 124 260 prescriptions in 19 hospitals over 7 days, 11 077 (8.9%) contained errors [24]. The error rates were 8.4% for first year doctors, 10.3% for second year doctors (when they become independent prescribers), 8.3% for those in fixed-term specialty training posts, and 5.9% for consultants. Experience helps, but education is still necessary. Indeed, of the five recommendations that the authors of that report made, four dealt with education. The fifth was that prescribing systems should be improved, such as by the introduction of a uniform prescription chart in all UK hospitals, as has already been done throughout Wales. This has not yet happened, although it has been the subject of a report [25]. A major challenge lies in persuading hospital prescribers that such a chart will be beneficial, of which there is already evidence from studies in Australia [26, 27], and persuading them that a chart that they themselves have not been involved in designing should be introduced. If electronic prescribing is introduced nationally, a uniform chart will certainly be needed, and the sooner a national printed chart is introduced the better.

Conclusions

Balanced prescribing is hard to achieve. It is underpinned by a knowledge and understanding of the basic principles of clinical pharmacology, of the properties of individual medicines, and of the pathophysiology of disease, and by careful attention to the diagnosis and to individual patient's needs, as dictated by the nature of the condition to be treated, co-morbidities, other therapy, and the patient's preferences and abilities. Careful attention to all facets of prescribing can improve the chances of benefit, reduce the risks of adverse reactions, and enhance adherence to therapy.

The challenges to improving prescribing include:

- the need to educate all prescribers in the basic principles, to ensure that they are well equipped to prescribe within the limits of their own knowledge and capabilities; this implies a need to institute adequate means of assessing prescribing abilities at both undergraduate and postgraduate levels;
- improving the quality of evidence available to guide adequate monitoring of drug therapy;
- finding ways of reducing the incidence of medication errors;
- the provision of high quality information that will at the same time guide prescribing decisions and be sufficiently flexible to allow prescribers to tailor therapy to the needs of the individual patient;
- overcoming the problems associated with introducing a uniform hospital prescription chart throughout the UK.

Competing Interests

There are no competing interests to declare.

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